K041548

AUG - 9 2004

Section B – Statements / Certifications

510(k) Summary

Submitter [807.92(a)(1)]:

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Contact Person [807.92(a)(1)]: **Hayoz Josef, Ph.D.**
Scientific Development & Product Mananger

Date prepared [807.92(a)(1)]: **June 4, 2004**

Trade, Common and Classification Name [807.92(a)(2)]:

Trade / Proprietary Name	Common / Usual Name	Classification Name	Product Code	Class	Regulation Number
Sentec Digital Monitor System Sentec Digital Monitor, V-Sign™ Sensor & Accessories	Cutaneous Carbon Dioxide Monitor	Monitor, Carbon-Dioxide, Cutaneous	73 LKD	II	21 CFR Part 868.2480
	Pulse Oximeter	Oximeter	74 DQA	II	21 CFR Part 870.2700
	Pulse Oximeter	Oximeter, Ear	74 DPZ	II	21 CFR Part 870.2710

Substantially Equivalent to [807.92(a)(3)]:
The Sentec Digital Monitor System combines the features of a pulse oximeter (sensor applied to the ear lobe) and a cutaneous carbon dioxide monitor. Thus it is a combination of i) a Pulse Oximeter and ii) a Cutaneous Carbon Dioxide Monitor. The Sentec Digital Monitor System is substantially equivalent to the combination of (applicable portions of) the following devices:

	Device	Manufacturer	Comment
K991644	MicroGas 7650 Transcutaneous Monitor	Linde Medical Sensors	These two devices are exactly the same devices (refer to 510k summary of K991644). Between the Linde MicroGas 7650 (K991644) and the Kontron MicroGas 7650 (P 810037/S007) are only labeling differences. The **PCO2 part** of these two devices is predicate to the PCO2 part of the Sentec Digital Monitor System.
P810037 / S007	MicroGas 7650 Transcutaneous Monitor	Kontron Instruments AG, Medical Sensors	
K972468	NPB-195 Pulse Oximeter	Nellcor Puritan Bennett Inc.	These two devices are predicate devices to the **pulse oximetry part** of the Sentec Digital Monitor System.
K944760	Dura-Y Oxygen Transducer, Ear Clip	Nellcor	

Reason For Submission: New Device

Description of the device [807.92(a)(4)]:

The SenTec Digital Monitor System (SDMS) is a device consisting of a stand-alone monitor, a digital sensor, a connecting cable, and accessories for sensor application and maintenance. The SDMS is designed for the continuous and non-invasive monitoring of carbon dioxide partial pressure (PCO2), functional oxygen saturation (SpO2) and pulse rate (PR), using a single, digital sensor (V-Sign™ Sensor).

The V-Sign™ Sensor combines within one digital sensor the technology to measure cutaneous PCO2 with the optical elements (LED, photodetector) needed for pulse oximetry. The PCO2 measurement of the V-Sign™ Sensor is based on a Stow-Severinghaus type PCO2 sensor. The V-Sign™ Sensor slightly raises the temperature at the monitoring site to achieve local arterialisation of the skin, which is required for the cutaneous PCO2 measurement. Safe temperature operation is achieved using two independent measurement and control systems. The sensor is applied to the patient's ear lobe using SenTec's single patient use Ear Clip and a thin layer of Sensor Gel.

The Sentec Digital Monitor (SDM) is equipped with an integrated calibration unit, the Docking Station, allowing a fully automatic pCO2 sensor calibration with Sentec's Service Gas. If stored in the Docking Station the V-Sign™ Sensor is periodically recalibrated. These features ensure that the V-Sign™ Sensor is continuously ready to use.

The V-Sign Disposable Set provides a straight-forward preparation of the V-Sign™ Sensor- with the ease of 4 "Push-and-Turn" procedures, all necessary steps to exchange the sensor's membrane are performed.

Intended Use [807.92(a)(5)]:

The SenTec Digital Monitor System (*comprising the SenTec Digital Monitor, V-Sign™ Sensor* and *Accessories)* is indicated for continuous non-invasive patient monitoring. The SenTec Digital Monitor System is indicated for use in hospitals, hospital-type facilities, intra-hospital transport environments, and, if under clinical supervision, home environments. The SenTec Digital Monitor System is for prescription use only.

The *V-Sign™ Sensor*, model VS-A/P, is indicated for use with the Sentec Digital Monitor when continuous non-invasive carbon dioxide tension, oxygen saturation and pulse rate monitoring are required for adult through pediatric patients.

SenTec's *Ear Clip*, model EC-A/P, is intended for use with the *V-Sign™ Sensor* when continuous, non-invasive carbon dioxide tension, oxygen saturation and pulse rate monitoring are required. The *Ear Clip* is for single-patient use and indicated for patients weighing 10 kg or more, using exclusively the ear lobe as a monitoring site. The use of the SenTec *Ear Clip* is contraindicated for patients whose ear-lobes are very small (resulting in inadequate sensor application).

Caution: Federal law restricts this device to sale by or on the order of a physician.

Comparison to predicate device [807.92(a)(6)]:

The SenTec Digital Monitor System has the same indications for use as a combination of the predicate devices.

The indicated patient population of the Sentec Digital Monitor System is similar to that of the predicate devices, i.e. the entire patient population for the PCO2 part of the MicroGas 7650 and patients weighing more than 30 kg for the NPB-195 pulse oximeter with the Dura-Y Sensor applied to the ear lobe with the Dura-Y Ear Clip.

The technological characteristics of the Sentec Digital Monitor System and the two predicate devices are essentially the same. All relevant features of the MicroGas 7650 with COMBI•M 82 sensor and of the NPB-195 with the Dura-Y Sensor and the Dura-Y Ear Clip were combined and are included in the Sentec Digital Monitor System. In particular these are:

- same principles of operation (2 wavelength SpO_2 measurement, and PCO_2 electrode technology)
- similar sensor application means [adhesive Ear Clip versus adhesive Ring (MicroGas) and Ear Clip (Nellcor)]
- calibration unit integrated in monitor
- similar alarms and messages as predicate devices

- similar accessories for maintenance: membrane exchange tool, sensor contact gel, service gas
- all devices are portable stand-alone monitors

The method of operation of the Sentec Digital Monitor System is the same as a combination of both predicate devices:

A. Sensor preparation
- need to calibrate the PCO2 part of the sensors
- need to remembrane the sensor
- need to store the sensor in the calibration unit with the monitor switched-on
- need to clean the sensor prior inserting it into the calibration unit

B. Monitoring
- application of the sensor to a site using a specific sensor application means
- need to use a contact liquid that traps gases diffusing out of the skin
- need to use a warmed sensor
- need to inspect the application site regularly (Site Timer)

The materials used in both devices are similar. The instruments cases are formed of thermoplastic materials. The electronics within the instruments are standard electronic parts (resistors, capacitors, integrated circuits, wiring, connectors, etc.).

Non-Clinical Performance data [807.92(b)(1)]:

Standards Testing (Electrical, Mechanical and Environmental)
The Sentec Digital Monitor System was tested to applicable standards for medical device Electrical Safety, Electromagnetic Compatibility, Shock and Vibration, and Environmental Temperature and Humidity. Additionally the device was tested in accordance with the Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO2) and Oxygen (PcO2) Monitors; Guidance for Industry and FDA, December 13, 2002. The device passed all tests.

Biocompatibility Testing
Biocompatibility testing has been conducted for all patient contact materials in compliance with ISO 10993-1:1997. All materials met Biocompatibility requirements.

Bench Testing
Bench testing verified that the Sentec Digital Monitor System measured pulse rate values within ±3 digits of a laboratory pulse rate simulator.

Clinical Performance data [807.92(b)(2)]:

Clinical studies were performed using the Sentec Digital Monitor System with healthy adult volunteer subjects who were subjected to progressive induced hypoxia against arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter as reference. The clinical study data furthermore support the performance of the PCO2 and pulse rate measurements. The results from the clinical studies show that the reported saturation values from the Sentec Digital Monitor System meet specified accuracy requirements.

Conclusion[807.92(b)(3)]:

The results of all **laboratory tests** demonstrate that Sentec Digital Monitor System meets specified requirements.

The **clinical and non-clinical testing** performed demonstrates that the Sentec Digital Monitor System is safe, effective and performs as well as the two predicate devices, and therefore, it is substantially equivalent to the predicate devices.

Other information [807.92(d)]:

Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2004

Sentec, Incorporated
C/O Mr. Stephen Gorski
Imagenix, Incorporated
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K041548
Trade/Device Name: Sentec Digital Monitor System (SDMS)
Regulation Number: 21 CFR 868.2480, 870.2710
Regulation Name: Cutaneous Carbon Dioxide ($PcCO_2$) Monitor
Regulatory Class: II
Product Code: LKD, DPZ
Dated: June 4, 2004
Received: June 9, 2004

Dear Mr. Gorski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Sentec Digital Monitor System (SDMS)

Indications for use:

The SenTec Digital Monitor System (*comprising the SenTec Digital Monitor, V-Sign™ Sensor* and *Accessories)* is indicated for continuous non-invasive patient monitoring. The SenTec Digital Monitor System is indicated for use in hospitals, hospital-type facilities, intra-hospital transport environments, and, if under clinical supervision, home environments. The SenTec Digital Monitor System is for prescription use only.

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Prescription Use ____X____ AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K041548